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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NGUYEN, CAMTU TRAN	
ART UNIT	PAPER NUMBER
3772	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/839,643	KEREN ET AL.	
	Examiner	Art Unit	
	Camtu T. Nguyen	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49,50,59,68-70,73,78,84,86-89,92,97-103,107 and 108* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49,50,59,68-70,73,78,84,86-89,92,97-103,107 and 108* is/are rejected.

7)☒ Claim(s) *49* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6.1.10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This Office Action is responding to applicant's amendment filed on 6/17/2010. Claims 49, 103, 107-108 have been amended. Claims 51-58, 60-67, 71-72, 74-74, 79-83, 85, 90-91, 93-96, 104-106, 109-112 have been cancelled.

The claims indicated in the previous Office Action as having allowable subject matter have been regrettably withdrawn in view of the following interpretation of the Wolf reference in the following rejection.

Claim Objections

Claim 49 is objected to because it recites **a heart chamber**, did applicant intent to recite the **left atrium** instead? Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claim 59 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: a pressure sensor causing the valve open when the pressure differential is 12 mmHg between the left & right atria.

Claim 92 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the

claim(s) in independent form. Specifically, dependent claim 92 recites the valve opens during diastole, and its independent claim 84 recites the valve opens NOT during normal diastole, clearly claim 92 does not further limiting claim 84.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 49-50, 59, 69-70, 73, 78, 84, 86-89, 92, 97-102-103, and 107-108 are rejected under 35 U.S.C. 102(e) as being anticipated by Wolf et al (U.S. Patent Application Publication No. US 2002/0165606 A1).

Wolf et al discloses in Figures 2-4 & 7 a differential pressure regulating device comprising a shunt (12, 34) positioned in heart wall between two heart chambers or vessels to enable blood/fluids to flow therebetween (paragraph 0028), and an adjustable valve device (10) to regulate the blood/fluids.

Regarding claim 49 requiring the shunt between a left atrium & a right atrium of the heart, Wolf et al reference discloses the "chambers" are referred to the left & the right chambers (paragraph 0028 line 1-3) and the "heart wall" is referred to interatrial septum (paragraph 0029), which is between the left atrium & the right atrium, as such, the Wolf et al's shunt (12, 34) meets the limitations in claim 49.

Regarding claim 49 reciting the shunt **enabling blood flow between the left atrium & the right atrium and decreasing blood pressure in an atrium**, Wolf et al reference discloses the high-pressure blood flow causes valve (10) of shunt (12, 34) to open, allowing blood flow between the left atrium & the right atrium, thereby, decreasing blood pressure in one of the atria.

Regarding claim 49 reciting **allowing an amount of blood suitable to reduce blood pressure in said left atrium, to flow from said left atrium to said right atrium via said shunt when a pressure differential between said left & said right atrium reaches a threshold thereby decreasing blood pressure in a heart chamber**, it is noted that claim 49 does not define what the pressure differential "threshold" between left atrium & right atrium must be is in order to reduce the blood pressure in the left atrium by allowing blood flow from the left atrium to the right atrium. By broad & reasonable interpretation of the "threshold" in claim 49, the Wolf reference discloses the shunt (12) is elastically deform under contractive pressure of the heart muscle (paragraph 0041) such that pressure is built up in the left atrium until a pressure differential between the left atrium & the right atrium reaches a threshold, the shunt (12) will open allowing the blood in the left atrium to flow to the right atrium, thereby, reducing blood pressure in the left atrium.

The Wolf et al shunt (12, 34) would perform the method of decreasing blood pressure in a heart chamber.

Regarding claim 50, Figures 2-4 illustrates flared ends of the shunt anchored the shunt therethrough.

Regarding claim 59, the Wolf reference discloses the valve (32) of shunt (12) is open during systole of cardiac cycle and is close during diastole of cardiac cycle.

Specifically regarding the recitation **the valve being configured to open when a pressure differential between said left atrium & said right atrium is 12 mmHg or above**, applicant's specification discloses that during diastole, pressure in the left atrium normal is no more than 12 mmHg (page 5 lines 16-18), hence, such disclosure is consistent with Wolf's operation. Namely, the valve would open during when pressure differential is relatively high, more than normal 12 mmHg.

Regarding claim 69, this claim does not specifically recite a configuration or shape of the valve that allow passage small volume of the blood therethrough, therefore, the Wolf's valve (32) configured to & capable of allowing passage of a relatively small volume of blood relative to an ejection of volume of the heart.

Regarding claim 70, this claim does not specifically recite a length of the shunt device, therefore, Figure 1a illustrates the length of the shunt is not greater than a thickness of the septum.

Regarding claim 73, the Wolf's valve (32) is capable of gradual opening and/or closing.

Regarding claim 78, Figures 2-4 in the Wolf reference illustrates the flared ends of attached to opposite sides of the shunt (12).

Regarding claim 84, it is noted that this claim does not define what pressure level is during an exacerbated state of heart failure. In response to the limitations in claim 84, the Wolf's valve (32) closes under normal pressures of systole & diastole of cardiac cycles, as the heart chambers/atria demonstrate no pressure differential therebetween. On the contrary, the Wolf's valve (32) would open in response to a pressure build-up between the heart chambers/atria, a condition of exacerbated heart failure state. As such, the Wolf reference would decrease blood

blood pressure in a heart atria by implanting the valve (32) between the heart atria such that it response to the pressure differential therebetween.

Regarding claim 86, see rejection to claims 49 & 50 above.

Regarding claim 87, see rejection to claim 50 above.

Regarding claim 88, see rejection to claim 59 above.

Regarding claim 89, see rejection to claim 50 above.

Regarding 92, Wolf discloses in paragraph 0050 that the valve (32) can be biased to a closed position, wherein the valve is open allowing blood flow immediately precedes systole (during transitioning to diastole).

Regarding claim 97 reciting a sensor, Wolf et al discloses a sensor (30) positioned within the shunt (12), the sensor (30) senses electrical signals produced in the heart muscle, a state of the heart, and causes the valve (12) to open in response to the reading of the sensor (30), see paragraph 0050.

Regarding claim 98, the limitation **an exacerbated differential arterial pressure** has been broadly interpreted as high pressure differential between the heart atria, therefore, the Wolf's valve (32) would open in response to a pressure build-up between the heart chambers/atria, a condition of exacerbated heart failure state.

Regarding claim 99, the Wolf's valve (32) closes when the left atrium pressure is less than 12 mmHg.

Regarding claim 100, the valve (10) would open in response to a differential pressure between opposite ends of valve.

Regarding claim 101, Wolf discloses the shunt (12) is delivered through a coronary artery, typically by using a catheter, thereby, rendering the shunt (12) is implanted via a percutaneous procedure

Regarding claim 102, Wolf et al discloses shunt (12) in implanted in interatrial septum (paragraph 0029), which is in a transseptal hole.

Regarding claim 103, Wolf et al shunt (12), presented above, discloses shunt (12) is configured for positioning within a septum between atria of the heart (paragraph 0028-0030), a sensor (30) senses the electrical signals produced in the heart muscle, an actuator (36) to control the shunt. Regarding claim 103 reciting the sensor **indicating a pressure above 12 mmHg**, of which pressure is associated with the systole of cardiac cycle, such pressure has been broadly interpreted as high pressure or exacerbated heart failure pressure. With this interpretation in mind, the Wolf actuator (36) is adapted to control flow through the valve (32) of shunt (12) in response to systole of cardiac cycle (paragraph 0050).

Regarding claims 107-108, the pressures in these claims are in systole of cardiac cycle and the actuator (36) would open the valve during systole.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf et al (U.S. Patent Application Publication No. US 2002/0165606 A1), presented above, and further in view of Wilk (U.S. Patent No. 7,294,115).

Wolf et al discloses in Figures 2-4 & 7 a differential pressure regulating device comprising a shunt (12, 34) comprising all of the elements as recited in these claims including the shunt (12, 34) is positioned within a septum between a left atrium & a right atrium of the heart, except Wolf does not explicitly disclose the diameter of the shunt (12) is less than 5 mm.

Wilk discloses in Figures 1-5 shunts with valves to be in the heart wall (HW) from ventricle (LV) into coronary artery (CA), however, Wilk discloses that these shuts with valves may also be applied to the right and left atria (column 11 lines 64-67). Another embodiment of the shunt Figure 29 discloses shunt (312) having a diameter of 2.0 mm (column 27 lines 16-21), less than 5 mm, thereby, meeting claim 68.

Therefore, it would have been obvious to one skilled in the art to construct the Wolf's shunt (12) in the size taught by Wilk, as such would be comfortable to the patient when implanted.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Camtu T. Nguyen whose telephone number is 571-272-4799. The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Camtu T. Nguyen/
Examiner, Art Unit 3772

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772